4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0986]

Center for Devices and Radiological Health: Experiential Learning Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH or Center) is announcing the 2016 Experiential Learning Program (ELP). This training component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities to request to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the ELP.

DATES: Submit either an electronic or written request for participation in the ELP by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.

ADDRESSES: Submit either electronic requests to http://www.regulations.gov or written requests to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify requests with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christian Hussong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm.

5261, Silver Spring, MD 20993-0002, 240-402-2246, FAX: 301-827-3079, Christian.Hussong@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for helping to ensure the safety and effectiveness of medical devices marketed in the United States. Furthermore, CDRH assures that patients and providers have timely and continued access to high-quality, safe, and effective medical devices. In support of this mission, the Center launched various training and development initiatives to enhance performance of its staff involved in regulatory review and in the premarket review process. One of these initiatives, the ELP Pilot, was launched in 2012 and fully implemented on April 2, 2013 (78 FR 19711).

CDRH is committed to advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. This component is a collaborative effort to enhance communication and facilitate the premarket review process. Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, regulatory impacts, and regulatory needs.

These formal training visits are not intended for FDA to inspect, assess, judge, or perform a regulatory function (e.g., compliance inspection), but rather, they are an opportunity to provide CDRH review staff a better understanding of the products they review. Through this notice,

CDRH is formally requesting participation from companies, academia, and clinical facilities, including those that have previously participated in the ELP or other FDA site visit programs.

II. CDRH ELP

A. Areas of Interest

In this training program, groups of CDRH staff will observe operations at research, manufacturing, academia, and health care facilities. The focus areas and specific areas of interest for visits may include the following:

Table 1.--Areas of Interest--Office of Device Evaluation

Focus Area	Specific Areas of Interest
Usability testing	Observe usability testing throughout a device's life cycle and complex clinical simulations.
Reprocessing and reuse of single-use devices (SUDs)	Observe reprocessing and reuse of SUDs in a major health system (i.e. Hospital Reprocessor).
Transcatheter heart valves	Observe design, development, and testing of transcatheter heart valves, including pulmonic and aortic valve prostheses and related technology.
Cardiac electrophysiology (EP) diagnostic, mapping, and ablation devices	Observe clinical EP catheter laboratory and observe catheter ablation procedures (manual and potentially robotic); including EP Lab manager and practicing EP physicians.
Neurological medical devices--early feasibility clinical trials	Design, development, and testing of novel neurological medical devices qualified under early feasibility clinical trials.
Neurostimulators and neuroprosthetics including brain-to-computer interface (BCI)	Design, development, and testing of neurostimulators and neuroprosthetics including BCI technologies.
Non-clinical testing--animal model	Observe non-clinical animal model testing demonstrating the performance of bone void fillers in the posterolateral spine.
Patient matched orthopaedic implants	Observe the patient matched process from the surgeon's decision to utilize patient matched technology through surgery.
Auditory brainstem implants (ABI)	Design, development, and testing of ABI and observe the surgical procedure and a post-implant programming session.
Contact lens care products	Design, development, and testing of contact lens care products and observe non-clinical testing for these devices.
Surgical mesh devices	Design, development, and testing of surgical mesh indicated for gynecologic and urologic indications.
Feeding tubes	Design, development, and testing of nasogastric tubes, nasojejunal tubes, and percutaneous endoscopic gastrostomy tubes.

Focus Area	Specific Areas of Interest
Robotically-assisted surgical devices (RASD) and surgical simulators in robotic surgery	Design, development, testing, and validation of emerging RASD and mechanized laparoscopic technologies adopted from other specialties and new-area specific; and surgical simulators incorporating tissue models and force feedback mechanism or haptic technology to reduce learning curve in robotic surgery.
Biological evaluation (i.e., biocompatibility) and viral inactivation of medical devices	Observe all implanted, surface contacting, and external communicating devices.

Table 2.--Areas of Interest--Office of In Vitro Diagnostics and Radiological Health

Focus Area	Specific Areas of Interest
Continuous glucose monitoring systems and insulin pumps	Design and development in-process, and finished device testing of continuous glucose monitoring systems and insulin pumps.
Urine test strips and readers	Design and development in-process, and finished device testing of urine test strips and readers.
Prothrombin (PT)/international normalized ratio (INR) devices	Design and development in-process, and finished device testing of PT/INR devices.
Direct anticoagulants (detection)	Observe the detection of direct anticoagulants.
Antimicrobial susceptibility testing (phenotypic, biochemical, and molecular detection)	Observe clinical microbiology laboratory, contract research organization (CRO), and/or industrial setting where antimicrobial susceptibility testing is being applied.
Next generation sequencing (NGS)	Observe clinical microbiology laboratory, CRO, and/or industrial setting where NGS is being applied.
Immunohistochemistry (IHC) reagents or digital pathology devices	Design, development, and testing of IHC reagents or digital pathology devices that are commonly used in pathology labs.
Cell-free DNA/RNA biomarker technology	Observe Clinical Laboratory Improvement Amendments labs involved with cfDNA, ctDNA, or miRNA for clinical diagnostics.
Radiological imaging equipment testing	Observe radiological imaging equipment (e.g. CT, MR, PET, fluoroscopy, etc.) testing and evaluation of particular consensus standards.
Radiation therapy equipment	Observe radiation therapy equipment (e.g., linear accelerator, proton beam therapy, brachytherapy) testing and evaluation.

B. Site Selection

CDRH will be responsible for CDRH staff travel expenses associated with the site visits. CDRH will not provide funds to support the training provided by the site to the ELP. Selection of potential facilities will be based on CDRH's priorities for staff training and resources

available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP and must also have a satisfactory compliance history.

III. Request to Participate

Submit requests for participation with the docket number found in the brackets in the heading of this document. Received requests may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

The request should include a description of your facility relative to focus areas described in table 1 or 2. Please include the Area of Interest (see table 1or 2) that the site visit will demonstrate to CDRH staff, a contact person, site visit location(s), length of site visit, proposed dates, and maximum number of CDRH staff that can be accommodated during a site visit. Requests submitted without this minimum information will not be considered.

Additional information regarding the CDRH ELP, including a sample request and an example of the site visit agenda, is available on CDRH's Web site at: http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.

Dated: March 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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